DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 2 7 1999

NDA 12-250/S-019

Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

Attention: Jill N. Sackett
Assistant Director, Regulatory Affairs

Dear Ms. Sackett:

Please refer to your supplemental New Drug Application (sNDA) dated April 11, 1990, received April 17, 1990, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Carbocaine (mepivacaine hydrochloride injection, USP).

Reference is also made to your letters dated June 3, and August 20, 1991, concerning additional sets of the "Special Supplement-Changes Being Effected". Further reference is made to August 2, and August 6, 1991, telephone conversations between the Agency and Dr. Linda Nardone requesting that the rationale for the package insert revision be provided.

We note that this supplement was submitted as a "Special Supplement-Changes Being Effected" under 2 1 CFR 3 14.70 (c).

This supplemental New Drug Application (sNDA) provides for an addition of the following statement to the **"Adverse Reactions-Neurologic"** section of the package insert. "Neurologic effects following other procedures of routes of administration may include persistent anesthesia paresthesia, weakness, paralysis, all of which may have slow, incomplete, or no recovery". Your submission stated April 11, 1990 as the implementation date for the change.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling April 11, 1990. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under.21 CFR 314.80 and 314.81.

If you have any questions, contact David Morgan, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research